Information Sheet – Diagnostic Testing for Influenza A/H7 by DoD Qualified Laboratories

using the

CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel – Influenza A/H7 (Asian Lineage) Assay

(For Emergency Use Only IAW Conditions of Authorization as specified in the FDA's Emergency Use Authorization)

On 19 April 2013, Secretary Kathleen Sebelius, Department of Health and Human Services, determined there is a significant potential for a public health emergency involving the avian influenza A (H7N9) virus that has a significant potential to affect national security or the health and security of United States citizens living abroad. On the basis of the determination, she declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of the avian influenza A (H7N9) virus. (http://www.phe.gov/emergency/news/healthactions/phe/Pages/H7N9-influenza-virus.aspx)

On 22 April 2013, the Food and Drug Administration (FDA) Commissioner, Dr. Margaret Hamburg, authorized emergency use of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel – Influenza A/H7 (Eurasian Lineage) for the presumptive detection of A (H7N9) influenza virus. (http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm)

Conditions of Authorization as specified in the 22 April 2013 Emergency Use Authorization (EUA) (**NOTE**: this is not a complete listing of the Conditions – see the EUA (http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM349060.pdf) for the full listing of Conditions):

- CDC will distribute the assay only to public health and other qualified laboratories. (Qualified laboratories are those that have the ABI 7500 FAST DX, whose laboratory personnel have successfully completed a training course provided by CDC instructors or designees, and which have successfully completed the analysis of a panel of influenza specimens to demonstrate assay performance competency.) Questions regarding DoD Qualified Laboratories (see list below) can be referred to the appropriate point-of-contact via e-mail inquiry submitted at FHPR.Communications@tma.osd.mil.
- The Influenza A/H7 (Asian Lineage) Assay is to be used in conjunction with CDC's existing influenza test kit (the Flu rRT-PCR Dx Panel) that is currently in use.
- Qualified laboratories will order the assay via the CDC's Influenza Reagent Resource, https://www.influenzareagentresource.org/. At this time, qualified laboratories will be able to order one (1) assay kit since actual use of the kit is expected to be sporadic and limited. **NOTE**: Use of this kit is for **diagnostic use only** in accordance with the conditions of authorization as specified in the EUA and the assay's instructions for use as distributed with the assay.
- The CDC will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which CDC becomes aware.

- Qualified laboratories will include with reports of the results the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients. Fact sheets may be provided as electronic attachments to the test results, as a hard copy document, or via provision of an internet link to a web site that has posted the documents.
- Qualified laboratories will have a process in place for reporting test results to healthcare providers and federal, state, and/or local public health authorities, as appropriate. **Laboratory management personnel shall coordinate with the installation's Public Health Emergency Officer regarding such reporting.**
- Qualified laboratories will collect information on the performance of the assay, and report to CDC any suspected occurrence of false positive or false negative results of which they become aware.
- Qualified laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The Influenza A/H7 (Eurasian Lineage) Assay **is to be used in conjunction with** the FDA-cleared CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (typing - A, B; subtyping - H1, H3, H1pdm09, H5 (Asian Lineage)). (http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM349065.pdf) Normal protocols for influenza testing should be followed with appropriate consideration of clinical and epidemiologic criteria. The Influenza A/H7 (Eurasian Lineage) Assay **should be used only after a type A, unsubtypeable result** is achieved with the CDC Human Influenza Virus RT-PCR Diagnostic Panel **and** the patient meets clinical and epidemiologic criteria for testing suspect specimens. The current CDC definition for a "Case Under Investigation" (http://www.cdc.gov/flu/avianflu/h7n9-case-definitions.htm) is:

> A patient with illness compatible with influenza meeting either of the following exposure criteria and for whom laboratory confirmation is not known or pending, or for whom test results do not provide a sufficient level of detail to confirm novel influenza A virus infection:
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> - A patient who has had recent contact (within ≤ 10 days of illness onset) with a confirmed or probable case of infection with novel influenza A (H7N9) virus.
>
> **OR**
>
> - A patient who has had recent travel (within ≤ 10 days of illness onset) to a country where human cases of novel influenza A (H7N9) virus have recently been detected or where novel influenza A (H7N9) viruses are known to be circulating in animals.

Test results from the Influenza A/H7 (Eurasian Lineage) Assay are considered to be **presumptive** at the current time. Confirmation of all novel influenza A (H7N9) viruses will initially be performed by CDC's Influenza Laboratory. Once appropriate diagnostic testing methodology has been identified by CDC, confirmation may be made by public health/qualified laboratories following CDC-approved protocols for detection of novel influenza A (H7N9) virus, or by laboratories using an FDA-authorized test specific for detection of novel influenza A (H7N9) virus.

Viral culture in laboratories – If infection with a novel influenza virus A is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses. Viral cultures **should not be attempted** in such cases **unless** a BSL3+ facility is available to receive and culture specimens.

Current CDC guidance for health professionals, clinicians, and laboratorians (including case definitions and diagnosis and laboratory testing guidance) can be found at http://www.cdc.gov/flu/avianflu/h7n9-virus.htm

Influenza Surveillance Activities: DoD public health and/or research laboratories that want CDC assistance regarding influenza surveillance activities may register at http://www.cdc.gov/flu/clsis/, the CDC's laboratory support for influenza surveillance site.

DoD Qualified Laboratories – Continental U.S.:

Walter Reed National Military Medical Center (WRNMMC)

Naval Infectious Diseases Diagnostic Laboratory (NIDDL)

Naval Medical Center - Portsmouth

Womack Army Medical Center (WAMC)

Dwight David Eisenhower Army Medical Center (DDEAMC)

U.S. Air Force School of Aerospace Medicine (USAFSAM)

Carl R. Darnall Army Medical Center (CDAMC)

Brooke Army Medical Center (BAMC)

William Beaumont Army Medical Center (WBAMC)

Madigan Army Medical Center (MAMC)

Naval Health Research Center (NHRC)

Tripler Army Medical Center (TAMC)

DoD Qualified Laboratories – Outside Continental U.S.:

Brian Allgood Army Community Hospital (BAACH)

Naval Hospital – Yokosuka

1900th Medical Detachment – Camp Buehring (tentative)

Naval Medical Research Unit 3

Naval Medical Research Unit 6

Landstuhl Regional Medical Center (LRMC)